DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2014

Covidien
Mr. Michael Koczocik
Product Specialist, Regulatory Affair
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K142869
Trade/Device Name: Premium Surgiclip™ III
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 30, 2014
Received: October 1, 2014

Dear Mr. Koczocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indication for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Premium Surgiclip™ III

Indications for Use *(Describe)*

The Premium Surgiclip™ III clip applier has application in many types of surgical procedures to occlude vessels and other tubular structures and for vagotomy, sympathectomy, and radiographic markings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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6. 510(k) Summary

This 510(k) summary of data used to demonstrate substantial equivalence is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98

NAME:	Covidien
ADDRESS:	60 Middletown Avenue North Haven, Connecticut 06473 USA
CONTACT PERSON:	Michael Koczocik Product Specialist, Regulatory Affairs
PHONE NUMBER:	203-492-6312
FAX NUMBER:	203-492-5029
DATE PREPARRED:	September 30, 2014
TRADE/PROPRIETARY NAME:	Premium Surgiclip™ III
COMMON/USUAL NAME:	Implantable Clip, Applier
CLASSIFICATION NAME:	Implantable Clip
PRODUCT CODE:	FZP
CLASSIFICATION PANEL NAME:	General and Plastic Surgery
FDA PANEL NUMBER:	79
DEVICE CLASS:	Pursuant to 21 CFR § 878.44300, an Implantable clip is a Class II device
PREDICATE DEVICE(S):	Premium Surgiclip™ Small 9.0” Clip Applier [K853650] (formerly AutoSuture™ Hemostatic Clips)
DEVICE DESCRIPTION:	The Premium Surgiclip™ III clip applier consists of an applier shaft with attached handles and integrated cartridge containing 20 titanium clips. The clip applier jaw is placed around a vessel or other tubular structure. As the handles of the

	applier are brought together, the clip is closed around the vessel or structure. The device contains a ratchet mechanism to ensure that a clip is not allowed to release until a full handle squeeze is applied. As the handles are released, a new clip is automatically loaded into the clip applier jaw. After the last clip is used, the device is designed to lockout which prevents the hands from being closed.
INTENDED USE:	The Premium Surgiclip™ III clip applier has application in many types of surgical procedures to occlude vessels and other tubular structures and for vagotomy, sympathectomy and radiographic markings.
SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICE(S):	The proposed device (Premium Surgiclip™ III clip applier) is a design modification to the predicate Premium Surgiclip™ (formerly AutoSuture™ Hemostatic Clips) cleared under [K853650] clip applier, while maintaining the same technological characteristics. Modifications have been made to the jaw to accommodate the clip feeding mechanism and jaw closing mechanism. Modifications to the clip geometry have been made to increase retention forces. The dimensional characteristics of the clips have changed slightly. The addition of a ratcheting mechanism has been introduced which prevents the jaws from opening until the handles have been squeezed and the clip has been fully formed.
MATERIALS:	All components of the Premium Surgiclip™ III clip applier are comprised of materials which are in accordance with ISO 10993-1.
PERFORMANCE DATA:	Bench performance evaluations were completed to show Premium Surgiclip™ III is substantially equivalent to the predicate device and performs as intended.
	The tests performed to show substantial equivalence of the Premium Surgiclip™ III clip applier to the predicate device are as follows:

In-vitro

- Clip over clip
- Jaw side load
- Jaw deflection
- Clip twist resistance
- Firing force
- Clip formation
- Clip security

– *In-vivo*

- Hemostasis
- Clip security
- Clip Removal
- Jaw twist deflection resistance

CONCLUSION:

The results of the performance and comparative testing described above demonstrate that the Premium Surgiclip™ III clip applier is substantially equivalent to the predicate device, AutoSture™ Hemostatic Clips cleared under [K853650].